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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/845,416	04/30/2001	Xiao Xiao	DE1253	4144

7590

06/12/2002

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EXAMINER

WHITEMAN, BRIAN A

ART UNIT	PAPER NUMBER
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1635

DATE MAILED: 06/12/2002

8

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 09/845,416	Applicant(s) XIAO, XIAO	
	Examiner Brian Whiteman	Art Unit 1635	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-28 is/are pending in the application.
- 4a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☐ Claim(s) ____ is/are rejected.
- 7) ☐ Claim(s) ____ is/are objected to.
- 8) ☒ Claim(s) 1-28 are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 11 October 2001 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on ____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. ____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s) ____. |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449) Paper No(s) ____. | 6) <input type="checkbox"/> Other: |

DETAILED ACTION

Claims 1-28 are pending.

Election/Restrictions

Restriction to one of the following inventions is required under 35 U.S.C. 121:

- I. Claims 1-17 and 24-28, drawn to an isolated nucleic acid sequence comprising: a) a N-terminal domain of a dystrophin gene or a modified N-terminal domain of the dystrophin gene; b) four to six rod repeats of the dystrophin gene; c) an H1 domain of a dystrophin of a dystrophin gene and an H4 domain of the dystrophin gene; and d) a Cysteine-rich domain of the dystrophin gene, classifiable in class 536, subclass 23.1.
- II. Claims 1-2 and 14-15, drawn to an isolated nucleotide sequence comprising: a) a N-terminal domain of an utrophin gene; b) rod repeats of the utrophin gene; c) an H1 domain of a dystrophin of a dystrophin gene and an H4 domain of the dystrophin gene; and d) a Cysteine-rich domain of the utrophin gene, classifiable in class 536, subclass 23.1.
- III. Claims 18-23, drawn to a method of treating Duchenne muscular dystrophy and Becker muscular dystrophy in a mammalian subject, comprising: (i) providing a vector comprising a dystrophin mini-gene operably linked to an expression control element; (ii) administering the vector of (i) to the mammalian subject, wherein the dystrophin mini-gene has fewer than 5,000 nucleotides comprising: a) a N-terminal domain of a dystrophin gene or a modified N-terminal domain of the dystrophin gene; b) four to six rod repeats of the dystrophin gene; c) an H1

domain of a dystrophin of a dystrophin gene and an H4 domain of the dystrophin gene; and d) a Cysteine-rich domain of the dystrophin gene, classifiable in class 514, subclass 44.

The inventions are distinct, each from the other because of the following reasons:

As set forth in *In re Harnisch* (631F.2d 716 206 USPQ 300 (CCPA 1980), see MPEP 803.02, unity of invention exists for all species in a claim (1) shows a common utility, and (2) share a substantial structural feature disclosed as being essential to that utility.

In view of *In re Harnisch*, claim 1 lacks unity of invention for the following reasons: 1) an isolated nucleic acid sequence comprising: a) a N-terminal domain of a dystrophin gene or a modified N-terminal domain of the dystrophin gene; b) four to six rod repeats of the dystrophin gene; c) an H1 domain of a dystrophin of a dystrophin gene and an H4 domain of the dystrophin gene; and d) a Cysteine-rich domain of the dystrophin gene, 2) an isolated nucleotide sequence comprising: a) a N-terminal domain of an utrophin gene; b) rod repeats of the utrophin gene; c) an H1 domain of a dystrophin of a dystrophin gene and an H4 domain of the dystrophin gene; and d) a Cysteine-rich domain of the utrophin gene. Both nucleotide sequences do not share a substantial structural feature disclosed as being essential for that utility. The nucleotide sequences only share around 200 nucleotides (H1 and H4) out of about 4,000+ nucleotides (which is roughly about 5% identity) because H1 and H4 are about 100 nucleotides (See page 1 of the as-filed specification and Figure 1). Therefore in view of *In re Harnisch*, claim 1 lacks unity of invention and is separated into distinct groups as shown in Groups I and II.

Inventions I and III are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the

product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case, the isolated nucleotide sequence encoding a dystrophin mini-gene can be used in materially different processes; for example, the mini-gene can be used to produce antibodies, a polypeptide for use in a method of polypeptide therapy, or in Invention III.

Inventions II and III are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case, the isolated nucleotide sequence encoding an utrophin mini-gene can be used in materially different processes; for example, the mini-gene can be used to produce antibodies or a polypeptide for use in a method of polypeptide therapy.

Because these inventions are distinct for the reasons given above and the literature search required for Group I is not required for Groups II-III, restriction for examination purposes as indicated is proper.

It would be unduly burdensome for the examiner to search and consider patentability of all of the presently pending claims, a restriction for examination purposes as indicated is proper.

Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

Applicant is reminded that upon cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 C.F.R. § 1.48(b) if one or more of the

currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a diligently filed petition under 37 C.F.R. § 1.48(b) and by the fee required under 37 § 1.17(h).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Kay Pinkney whose telephone number is (703) 305-3553.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Brian Whiteman whose telephone number is (703) 305-0775. The examiner can normally be reached on Monday through Friday from 8:00 to 5:00 (Eastern Standard Time), with alternating Fridays off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's mentor, primary examiner, Dave Nguyen can be reached at (703) 305-2024.

If attempts to reach the primary examiner by telephone are unsuccessful, the examiner's supervisor, John L. LeGuyader, SPE - Art Unit 1635, can be reached at (703) 308-0447.

Papers related to this application may be submitted to Group 1600 by facsimile transmission. Papers should be faxed to Group 1600 via the PTO Fax Center located in Crystal Mall 1. The faxing of such papers must conform with the notice published in the Official Gazette, 1096 OG 30 (November 15, 1989). The CM1 Fax Center number is (703) 308-4556.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.

Brian Whiteman
1635
6/10/02


DAVE T. NGUYEN
PRIMARY EXAMINER